

Remarks

Claims 34-36, 38, 40-41 and 74-81 are pending. All claims stand rejected under 35 U.S.C. § 103(a). Applicants respectfully disagree with the rejections of the claims based on obviousness and present detailed arguments below. A brief summary of the status of the claims and rejections follows.

Previously, the claims were rejected over the Rittman and Swanson documents in combination. After a telephonic interview, the claims were amended to address separate time periods for a tissue characterization and an ablation energy delivery. Now the claims are rejected under newly cited art. The newly cited art (Saul in combination with Chen), however, does not even address the tissue characterizing aspect recited in the claims. In fact, neither Saul nor Chen refer to the aspect of measuring a temperature change at the tissue site for any purpose as recited in claims 34 and 74, and neither address the "characterizing the tissue based on the temperature response" or "tissue characterization" aspect present in the claims. The "characterizing the tissue" aspect was added to claim 33, for example, in the Amendment of March 23, 2007. Finally, and perhaps most telling, neither document mentions the use of the presence of fat, amount of fat, flow of blood, tissue thickness and temperature of blood variables used to characterize the tissue in Applicants' claims.

Applicants will address each specific rejection below.

Rejections under 35 U.S.C. § 103(a)

Claims 34-36, 38 and 74-77 stand rejected as obvious over Saul in combination with Chen.

Claims 34 and 74 are independent with claims 35-36, 38, 40-41 and 75-81 depending therefrom.

In the Office action dated February 11, 2008, the Examiner alleges that "Saul, et al. teaches a method as claimed except epicardial placement (see column 3, line 38 to column 4, line 17). Chen et al. teaches the desirability of ablating on the epicardium or the endocardium. . . . It would have been obvious to use the low temperature and high temperature device and method of Saul et al. in the device and method of Chen et al., since this provides more reliable ablation of accessory pathways, as taught by Saul et al., thus producing a device and method such as claimed." (Office action at page 2). Applicants respectfully disagree for several reasons, as briefly noted above.

The case of KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007); 82 USPQ2d 1385, and recent guidance associated with it, has made explicitly clear that at least one aspect of an obviousness rejection has not changed. The initial burden remains on the Examiner to detail the appropriate supporting rationale when making a rejection based on Section 103: "Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, PTO-P-2007-0031, FR2007-57528-29, *quoting KSR at 1396*).

A close reading of the Saul reference does not support a legal conclusion of obviousness. The reference does not, as alleged by the Examiner, teach or suggest the method as claimed because Saul lacks several elements beyond epicardial placement. The addition of Chen (for epicardial placement) does not remedy those deficiencies.

Saul discusses a "low-temperature test application" and then if AP conduction returns, a "second radiofrequency application . . . made with a 70 degree C set point at the same site for a maximum of 60 seconds." (Saul, col. 3:65 – 4:6). This is simply a mapping technique to identify the correct ablation point, or it may be a trial-and-error approach to ablation. In either case, it does not relate to determining the appropriate

ablation temperature at the tissue site, for example, and it does not relate to any use of the presence of fat, amount of fat, flow of blood, tissue thickness and temperature of blood to characterize tissue. Significantly, there is no mention whatsoever in Saul and Chen of "presence of fat," "amount of fat," "flow of blood," "tissue thickness," or "temperature of blood." Saul also discusses that applications of energy were performed with an RF generator "in its temperature control mode, in which the generator automatically modulates the delivered power . . . using feedback from the catheter-embedded thermocouple to attempt to achieve a selected target temperature of between 45 degrees C. and 95 degrees C." (Saul, col. 3:59-64). The range for the "selected" temperature is so broad, one of skill in the art would immediately recognize it as not selective at all. Similarly, time periods in Saul are not selected but chosen from either five or ten seconds (see Example 2, col. 8:19-24). In fact, the "low temperature" tests in Saul are not discussed or suggested as a means for "determining" an ablation time and desired temperature as recited in claim 33, for example. They are used only to map a potential ablation site. Respectfully, that is not "the device and method as claimed" as alleged in the Office action.

Applicants' claims recite the measuring of a temperature change at the tissue site and characterizing the tissue using at least one of several variables. For example, one can measure a temperature at the tissue site over a period of time with multiple temperature sensors independently capable of measuring tissue temperatures at a number of different locations. (See, *for instance*, elements 336 in Figure 52 and lines 3-10 of page 31 of Applicants' specification as filed). Indeed, Applicants' claimed tissue characterization is a significant advance over anything explicitly discussed in Saul or any combination of Saul with the other cited references. That the analysis of the temperature response at the tissue site can be used to characterize the tissue is clearly described at page 35, lines 19-27 of the specification as filed. An analysis of the temperature response at the tissue site is certainly not suggested and it may not even

have been possible according to the text of Saul and the predetermined time periods, temperatures, and assumptions made in his method.

Specific recitations in the claims, which are absent from any reading of the cited art, are copied below :

analyzing the temperature change over the first period of time to determine a temperature response of the tissue at the tissue site; characterizing the tissue based on the temperature response of the tissue, temperature responses of other known tissue types and the input of at least one variable from a list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood; (from claim 34).

analyzing the temperature change to determine a tissue characterization; ablating tissue at the tissue with a second quantity of energy over a second period of time; the ablating step being carried out with input from at least one variable from a list of variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood (from claim 74).

Saul does not teach or suggest analyzing the temperature change in any way to produce any characterization of the tissue for determining an ablation time period and desired temperature. Thus, tissue characterization would not have been expected, predicted, or suggested as a method to determine ablation energy from a fair reading of Saul.

Additionally, there is no suggestion in Saul of any consideration of the tissue types and no suggestion of input from any variables possible in the tissue being

ablated, let alone fat content, blood flow or temperature or thickness of the tissue. Neither is there an enabling disclosure from Saul for this type of tissue characterization. Since Saul does not characterize the tissue using any of these variables it necessarily cannot *determin[e] an ablation time interval and a desired temperature to be delivered by the ablating element based on the tissue characterization* as recited in claim 34.

The Examiner further alleges that Chen "teaches the desirability of ablating on the epicardium or the endocardium" and that "it would have been obvious to the artisan of ordinary skill to employ the epicardial placement of Chen in the device and method of Saul." (Office action at page 2). However, at a minimum, the addition of Chen does not overcome the deficiencies argued above with respect to claims 34 and 74. Therefore, the combination of Saul and Chen does not teach, suggest, or render obvious Applicants' claimed invention. For at least this reason, the rejections based upon obviousness for claims 34 and 74 and those that depend from them (which are all of the pending claims) should be withdrawn.

As an additional reason that the combination of Saul with the other cited art fails to present a *prima facie* case of obviousness of the claims as a whole, the Saul reference is directed to an entirely different problem than Applicants' method. Therefore, there is no motivation or logical reason for one skilled in the art to look to the referenced art or modify it to arrive at even some of the allegedly common elements in Applicants' claims, as explained below.

Saul discusses a discovery that by locally 'stunning' cardiac tissue by low temperature energy "one can identify a preponderance of true positive conduction sites, and greatly limit the destruction of false positive or test sites implicit in existing cardiac ablation methods." (Col. 2:66-3:4). In that sense and as noted above, Saul is more akin to a "mapping" catheter performing electrophysiological mapping of accessory pathways (AP) through a "trial-and-error" method, which temporarily "stuns" tissue,

determines if an AP is blocked, and either ablates the site or moves on to a new location.

Applicants' claims recite a method for controlling an ablation at a pre-determined tissue site in order to enhance the safety and efficacy of the ablation by actually measuring tissue temperatures AND considering numerous other variables to analytically. If one were to follow the "mapping" procedure in Saul, an ablation technique suffers from exactly the same deficiencies that Applicants' methods overcome. Saul monitors temperature with a thermal sensor embedded in the electrode and hopes to avoid dangerous overheating through what is essentially a "trial-and-error" procedure using assumptions of the tissue temperature change or pre-determined ranges and time periods from experimental animal testing. Applicants' claims recite an analytical method that calculates the proper ablation time and technique, providing greater safety and efficacy. Accordingly, several aspects of Applicants' claimed methods are not even addressed in the cited art and no articulated reason with rational underpinning to support why they would have been adopted is present in this case. For this additional reason, claims 34 and 74 and their dependent claims are patentable.

For at least the reasons argued in detail above, Applicants submit that a *prima facie* case of obviousness has not been made.

Applicants' respectfully request that all the rejections based on Saul as a primary reference be withdrawn, which is all the current rejections. Each of the additional rejections are addressed below.

Claims 40 and 78 stands rejected as obvious over Saul in combination with Chen and further in view of Swanson.

Applicants have argued above to show that the Saul reference in combination with Chen does not teach, suggest, or render obvious Applicants' claims 40 and 78, which are dependent upon claims 34 and 74.

The Examiner additionally alleges that "Swanson et al. teaches the desirability of ablating on the epicardium and that less than half the total number of electrodes can be used." (Office action at page 2). However, at a minimum, the addition of Swanson does not overcome the deficiencies argued above with respect to the other limitations required by Applicants' claims 34 and 74. For at least this reason, the rejections based upon obviousness for claims 34 and 74 and those that depend from them (including claims 40 and 78) should be withdrawn.

Claim 41 and 79 stands rejected as obvious over Saul in combination with Chen and further in view of Ben Haim.

Applicants have argued above to show that the Saul reference in combination with Chen does not teach, suggest, or render obvious Applicants' claims 41 and 79, which are dependent upon claims 34 and 74.

The Examiner alleges that "Ben Haim teaches drawing tissue into a suction well prior to ablation." (Office action at page 3). However, at a minimum, the addition of Ben Haim does not overcome the deficiencies argued above with respect to the other limitations required by Applicants' claims 34 and 74. For at least this reason, the rejections based upon obviousness for claims 34 and 74 and those that depend from them (including claims 41 and 79) should be withdrawn.

Claim 80-81 stands rejected as obvious over Saul in combination with Chen and further in view of He.

Applicants have argued above to show that the Saul reference in combination with Chen does not teach, suggest, or render obvious Applicants' claims 80 and 81, which are dependent upon claim 74.

The Examiner alleges that "He et al teaches determining tissue parameters by cooling the tissue. It would have been obvious to employ the device for and step of cooling the tissue since this is the equivalent to the use of heating energy to do so, as taught by He et al, thus producing a method and device as claimed." (Office action at page 3). However, at a minimum, the addition of He does not overcome the deficiencies argued above with respect to the other limitations required by Applicants' claim 74.

Additionally, and independently of the reasons argued above, the cited references do not teach or suggest that the use of cooling energy is equivalent to the use of heating energy. In particular the Saul document is deficient in this regard. Saul explicitly states that it was based on the "discovery" that certain quantities of non-ablating heating energy can "stun" the target tissue and block accessory pathways. There is no teaching or suggestion in any of the cited documents that this "discovery" holds true for the application of cooling energy. Applicants respectfully submit that the Examiner has not met his burden of showing that cooling energy is equivalent to heating energy in the cited documents or why one of skill in the art would expect equivalent results. Therefore, for at least this additional reason, the rejections based on obviousness for claims 80-81 should be withdrawn.

For all of the reasons argued above, the rejections based upon obviousness for claims 34 and 74 and those that depend from them should be withdrawn.

Applicants submit that the application is in condition for allowance. Timely notification of allowability is requested.

No additional fees, requests for extension of time, other petitions, additional claim fees, or any other fees are believed to be necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicants hereby request any extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

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